

### REMARKS

Issues raised by the examiner are rendered moot by the foregoing. This is not to imply any agreement with any aspect of the office action. The previous claims met all requirements of 35 U.S.C.

Language in claims 109 and 111 regarding the enteric coating composition is based on conventional knowledge of the chemical composition of the enteric material utilized in Example 2, i.e., EUDRAGIT<sup>®</sup> L 30 D-55. This can be seen from the attached data sheets describing this well known enteric material, e.g., "EUDRAGIT L, Aqueous Dispersion, Data Sheet (Info LD-2/e), EUDRAGIT L 30 D" (two pages), at page 1, top and column 1; and "EUDRAGIT L, Aqueous Dispersion, Standards Sheet (Info LD-7/e), EUDRAGIT L 30 D" (two pages), at page 1, top and columns 1 and 2. (The notation "55" in the nomenclature used in the specification is an equivalent of the older nomenclature L 30 D, "55" simply referring to the pH (5.5) at which the enteric material becomes soluble.) Conventional values of area under the curve (AUC), maximum plasma concentration ( $C_{max}$ ) and the time to achieve  $C_{max}$ , i.e.,  $T_{max}$ , are taken directly from Figs. 7 and 8 of the application. Approximate AUC values were obtained by conventional weighing techniques and  $C_{max}$  and  $T_{max}$  by visual curve reading. The term "about" has its usual meaning in the field, e.g., roughly  $\pm 20\%$ , for example as used by FDA in its determinations of bioequivalency. The values from Figs. 7 and 8 are d-amphetamine levels to one of ordinary skill in the art, the mixture of amphetamine salts ("MAS" (page 16, lines 15-16)) used in the examples being the "mixture of four amphetamine salts" in ADDERALL<sup>®</sup> (page 4, lines 15-17) whose relative salt content is known. (See the PDR excerpts of record and the d-amphetamine plasma curves in the prior art, e.g., in Suc et al. also of record.)

Applicants maintain their position as set forth in the response submitted on October 24, 2002. The cited prior art does not render obvious any of the previously pending claims or the claims being added at this time, for the reasons set forth in the mentioned amendment. Thus, there is nothing in the prior art which would motivate a skilled worker to formulate the claimed active ingredients in the manner recited in the claims. See the case law described in the last response. Moreover, the previous claims and the current claims meet all requirements of 35

U.S.C. 112. The patent specification provides plentiful information whereby a skilled worker could, without undue experimentation, produce formulations which meet the requirements of the claims, e.g., the plasma levels as defined previously or in the current claims.

As for the comments of the Examiner on pages 4-6, the law has long been that functionality at the point of novelty is acceptable. *In re Swinehart*, 439 F.2d 210, 169 U.S.P.Q. 226 (CCPA 1971). Even if this doctrine were relevant and even if there were limits to it, these would not apply here, either for the previous claims or the current claims. The public is clearly informed of the limits of the claimed subject matter in both cases and of how to carry out the invention as claimed. Moreover, it is not clear to what multiple medication levels the Examiner refers. As is true for any open formulation claims, medicaments other than those specifically recited are included. However, the statute merely requires that the invention as recited in the claims be disclosed, not every possible variation which might be included. The Examiner also raises the issue of unexpected results. Applicants have not previously or now chosen to rely on any unexpected results.

The Commissioner is hereby authorized to charge any fees associated with this response or credit any overpayment to Deposit Account No. 13-3402.

Respectfully submitted,

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